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**SUMMARY OF SAFETY AND EFFECTIVENESS  
MENTOR H/S SILICONE GEL SHEETING FOR SCAR MANAGEMENT  
510(k) SUMMARY**

**1. Submitter's Data**

Mentor Corporation  
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Santa Barbara, CA 93111

Contact Person(s): Byron Wickett or Lynn Breckenridge

Telephone: (805) 681-6000

Date Prepared: February, 1996

**2. Device Name, Classification**

Name: Mentor H/S Silicone Gel Sheeting for Scar Management

FDA Classification: Class II, Elastomer, Silicone, for Scar Management  
(FDA Code 79MDA)

**3. Identification of Substantially Equivalent Devices**

DermaSof by McGhan Medical Corp.  
Epi-Derm Silicone Gel Sheeting by Biodermis Corp.  
TopiGel by CUI Corp.  
Sil-K by Degania Silicone

**4. Device Description**

The Mentor H/S Silicone Gel Sheeting for Scar Management is designed to treat hypertrophic and keloid scars. This therapy does not remove the scar, but will flatten and soften the scar tissue as well as return a more natural palor to the scar area. The material will be supplied sterile in sheets of silicone reinforced with polyester mesh. The sheets may be cut by the patient and/or the physician to a desired size to fit the scar treatment area.

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## INDICATIONS FOR USE

The Mentor H/S Silicone Gel Sheeting for Scar Management is indicated for treatment of hypertrophic and keloid scars. This therapy does not remove the scar but will flatten and soften the scar tissue as well as return a more natural palor to the scar area.

## 6. Contraindications for Use

Clinical contraindications for use of the Mentor H/S Silicone Gel Sheeting for Scar Management may include use by patients with medical conditions that would prevent them from using and cleaning the dressing properly. This product should not be applied over an open wound. The product should not be used if the patient is known to be allergic to silicone elastomers or if a rash develops.

## 7. Warnings, Precautions

Possible complications include:

skin rashes attributed to poor or insufficient hygiene  
skin rashes attributed to the gel sheeting being applied too tightly  
superficial maceration of the skin associated with an occlusive dressing  
pruritis

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